

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

IN RE NAMENDA DIRECT PURCHASER  
ANTITRUST LITIGATION

**Civil Action No.: 1:15-CV-07488-CM-RWL**

**MEMORANDUM OF LAW IN OPPOSITION TO FOREST'S MOTION TO  
BIFURCATE TRIAL INTO TWO PHASES**

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## I. INTRODUCTION

This is not the first time Forest has moved for bifurcation. On March 15, 2019, Forest orally moved to bifurcate Plaintiffs' interrelated reverse payment and hard switch claims. Tr. of March 15, 2019 at 5:3-16 (ECF No. 689). Forest unsuccessfully argued to the Court that the two claims are "completely unrelated when it comes to the facts," because "[t]hey were done years apart." *Id.* at 5:9-10. The Court rejected Forest's motion. *Id.* at 5:11-12 ("THE COURT: It doesn't make any difference. We're going to try them both."). The Court explained:

I am going to explain this to the jury. I'm not going to explain it to them once. I am probably going to explain it to them 30 times over the course of the trial and I can promise you that they're going to follow m[y] instruction. All right?

\* \* \*

I really think we're perfectly capable with appropriate limiting instructions of keeping the jury's focus on the issue as to which there has already been a collateral estoppel ruling. It's limited. It doesn't have to do with this. You can't think about it when you are thinking about that. You need to compartmentalize your brain. Juries are told to do that all the time.

*Id.* at 5:17-6:14. Forest failed to seek reconsideration within the 14-days set by Local Rule 6.3.

The Court's ruling was well-founded: limiting instructions suffice to focus juries on the applicability of particular evidence to particular claims, even in complex multi-defendant cases and criminal cases in which defendants are clothed with Fifth and Sixth Amendment protections. *See, e.g., United States v. Pinto-Thomaz*, 2019 U.S. Dist. LEXIS 46206, at \*11 (S.D.N.Y. Jan. 14, 2019) (prejudicial spillover argument rejected because "in this Court's experience, juries are not only able to 'compartmentalize' as required, but do it with care and, frequently, visible results in the form of verdicts that distinguish among the defendants.") (quotation omitted).

Now, Forest has filed an untimely motion for reconsideration, making the same arguments it made on March 15. Plaintiffs have two basic responses. First, Forest has not come

close to meeting its burden to show entitlement to severance or bifurcation, a burden that is notoriously heavy. Second, Forest is wrong that the reverse payment and hard switch claims here are “separate” or “distinct.” To the contrary, they are closely interrelated: the delay of generic IR competition brought about by the reverse payment provided Forest the necessary time to deploy the hard switch so that, when the delayed IR generics belatedly launched, XR had already overtaken IR and limited the competition the IR generics could create. The Court recognized this in denying summary judgment:

Plaintiffs allege that Forest engaged in a two-part anticompetitive scheme to improperly block generic competition for Namenda IR by: (1) conspiring with manufacturers of generic versions of Namenda IR to drop their legal challenges to the '703 Patent and delay launch of generic versions of Namenda IR until an identical date three months after the expiration of the '703 Patent; and (2) ***using this improperly obtained period of additional exclusivity*** to launch the successor branded product, Namenda XR, in order to force the conversion of the market from Namenda IR to the clinically equivalent Namenda XR (hereinafter the “hard switch”) before market entry of the generic versions of Namenda IR.

*In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 167 (S.D.N.Y. 2018)

(emphasis added). The Court also recognized this in denying Forest’s motion to dismiss:

the settlement agreements allegedly had a second anticompetitive effect, apart from foreclosing a challenge to the viability of Forest’s patent: allowing the Company to complete its anticompetitive “hard switch” strategy.

*Sergeants Benevolent Ass’n Health & Welfare Fund v. Actavis, PLC*, 2016 U.S. Dist. LEXIS 128349, at \*49 (S.D.N.Y. Sep. 13, 2016). *See also id.* 2018 U.S. Dist. LEXIS 220574, at \*3-4 (S.D.N.Y. Dec. 26, 2018) (“With [the settlements], Forest bought itself time to gain regulatory approval for a new, once-a-day Namenda XR formulation and to pull from the market the old, twice-a-day Namenda IR formulation.”). As the Court recognized, the reverse payment and the delay it created were integral to the success of the hard switch.

Nor will Forest's proposed phasing conserve judicial resources. Forest's proposed two-phased trial would require the jury and Court to consider two openings, two closings, two jury charges, two sets of deliberations, and two rounds of directed verdict motions as opposed to one. Moreover, several fact and, as Forest acknowledges, expert witnesses would need to be recalled for the second phase. *See, e.g.*, Mot. at 8 ("The fact that a few experts may be required to testify twice does not weigh against bifurcation because they are paid witnesses.").

Forest has utterly failed in its burden to show that this case presents a "truly extraordinary situation[s]" for which bifurcation, with its inherent inefficiencies, is reserved. *In re Blech Sec. Litig.*, 2003 U.S. Dist. LEXIS 4650, at \*33-34 (S.D.N.Y. Mar. 26, 2003) (quotation omitted). Forest's motion to reconsider is untimely, inapt, and contrary to the rules. It should be denied.

## **II. FACTS**

Contrary to Forest's assertions, the evidence at trial will show that the delayed generic IR competition from the reverse payment was part of the planned conversion to Namenda XR.

Forest knew that once it launched Namenda XR, it could face another set of legal challenges to the '703 patent — this time from generic Namenda XR ANDA filers. The reverse payment allowed Forest to avoid this risk because, by delaying generic competition for Namenda IR until 2015, Forest could then safely delay launching and converting the IR market to Namenda XR (which received FDA approval in 2010) until June 2013, and continue meanwhile to reap monopoly profits from Namenda IR. The delay in generic IR competition also allowed Forest time to obtain U.S. Patent No. 8,039,009 for Namenda XR, which did not suffer from the fatal flaws of the '703 patent, and which expired a decade after the '703 patent.

In a draft letter to Forest's Board, David Solomon (Forest's Vice President of Business Development and Strategic Planning) described the connections between delayed generic

Namenda IR competition from the patent settlements, the desire to preclude additional challenges to the '703 patent (*i.e.*, the “base patent”), and the plan to convert the market to Namenda XR using optimal timing:

It is clear from a commercial perspective that the sooner we launch [Namenda XR], the better — so we have the longest possible runway to convert business to the XR before the immediate release version goes generic . . . However, there are significant IP considerations that must be taken into account. First, our settlements in the original Namenda litigation were for the immediate release version only, and we would not want, through the launch of the XR, to give the generics another opportunity to attack the base patent and, if effective, open the door for early generics of the base Namenda product . . . Ultimately, I was able to bring the sides [within Forest] together on this and reach consensus around a launch in mid-2013, approximately 18 months before immediate release generics enter the market.

Ex. 1 (Exhibits are appended to the accompanying Litvin Decl.), FRX-AT-01684785 at -790.

Forest also used the delay in generic IR competition brought about by the reverse payment to maximize managed care’s receptivity to Namenda XR when it launched. Forest had learned that managed care would restrict coverage of a product line extension (like XR) if generics of the original drug (IR) were expected in the market in less than 18 months. Ex. 2, FRX-AT-01606209-10 (June 13, 2012 email on market research). The delay brought about by the reverse payment allowed Forest to time the launch of Namenda XR to be at least 18 months before generic entry, and allowed Forest time to convince managed care to add Namenda XR to formularies contemporaneously with the launch of XR. Ex. 3, FRX-AT-01775214-18 at 15 (Mark Devlin’s June 2013 Namenda XR launch speech noted that Forest’s account managers “have been promoting Namenda XR to their accounts for several quarters now and working hard to line up as much unrestricted access as possible before the June launch meeting . . . and we’ve been pretty successful”).



Yet, despite “successfully” attaining favorable XR formulary access by delaying generic IR entry, Forest was disappointed in the IR-to-XR conversion rate, and resorted to the unlawful hard switch. Ex. 4, FRX-AT-01779417-19 (Oct. 18, 2013 email re hard switch decision).

Contrary to Forest’s argument that Mr. Solomon (and other witnesses) were not involved in the hard switch, as far back as 2008 (*i.e.*, prior to the 2010 Forest-Mylan patent settlement) he discussed IR-to-XR “conversion strategies,” including XR market share projections and launch timelines. *See, e.g.*, Ex. 5, FRX-AT-04615282 at -288 (Feb. 21, 2008 email to *inter alia* William Meury, Rachel Mears, Mr. Solomon and Robert Carnevale about possible XR launch timing, expected IR-to-XR conversion, and factoring in patent litigation and 30 month stays); Ex. 6, FRX-AT-04614356 at -357 (Feb. 21, 2008 memorandum from Ms. Mears to Messrs. Solomon, Meury and Carnevale referencing “the conversion strategy for the [XR] formulation.”). Indeed, Mr. Solomon admitted that “when we were beginning to plan for the launch of the product, of the extended release product, one of the questions that we began to consider was whether we might remove the immediate release tablet.” Ex. 7, David Solomon Dep. Tr. at 56:22-57:9.

Mr. Solomon was equally involved in early discussions of the hard switch analogues. Ex. 8, FRX-AT-01775151-61 (Sept. 29, 2012 email regarding “Examples of follow-on strategy,” discussing search for “analogues of product conversion in the recent 5 years where the first product was pulled from market”). In late fall of 2013, Mr. Solomon and CEO Brent Saunders, communicated to Forest’s partner Merz that it would pursue the hard switch. Ex. 9, FRX-AT-01594102-03. Mr. Solomon followed up on Dec. 6, 2013, noting, “We want to go back to Merz for a royalty reduction on XR, since we will have to take a lower margin to achieve the hard switch.” Ex. 10, FRX-AT-01641750. Contrary to Forest’s argument, Mr. Solomon was involved throughout including in initial XR launch planning and forecasting, IR patent

settlements and the reverse payment (SJ Opp’n PSOF (ECF No. 613) ¶¶ 222-34), and the hard switch.

Nor was Mr. Solomon the only witness connecting the reverse payment and the hard switch. As Forest admits in its Interrogatory Responses, Mr. Devlin, whom Forest now asserts was involved only in the hard switch (Mot. at 7), does as well. Ex. 11, Forest’s Jul. 12, 2017 Supp’l Obj. and Resp. to Second Set of Interrogatories at 15. (Naming Messrs. Devlin, Solomon, Carnevale and Ms. Mears as knowledgeable of the Forest-Mylan Lexapro Amendment).

The delay from the reverse payment allowed Forest to gain the market share it ultimately obtained. Had generic IR not been delayed, Forest would not have had the time to prime managed care to treat Namenda XR favorably, and it would not have been able to impose the hard switch when physicians resisted the conversion, resulting in less conversion to XR.

### **III. ARGUMENT**

#### **A. Legal Standard for Bifurcation and Severance Under Rule 42(b)**

“Under Federal Rule of Civil Procedure 42(b), courts have the authority to grant a separate trial ‘in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy.’” *Blech*, 2003 U.S. Dist. LEXIS 4650, at \*31. However, “the presumption is that all claims in a case will be resolved in a single trial, and it is only in exceptional instances where there are special and persuasive reasons for departing from this practice that distinct causes of action asserted in the same case may be made the subject of separate trials.” *Id.* at \*32-34. *See also* Fed. R. Civ. P. 42(b), advisory committee note (“separation of issues for trial is not to be routinely ordered.”). Thus, “[b]ifurcation is the exception, not the rule, and the party seeking it bears the burden of establishing that it is warranted.” *Blech* at \*35-36. That burden is a “heavy” one. *See In re Lehman Bros. Holdings*,

*Inc.*, 2011 U.S. Dist. LEXIS 72125, at \*4-5 (S.D.N.Y. June 22, 2011) (“the party seeking bifurcation shoulders the heavy burden of establishing that bifurcation is warranted.”).

Courts “engage in a balancing test” to decide whether to bifurcate. *Blech*, 2003 U.S. Dist. LEXIS 4650 at \*32. The factors are:

- (1) whether the issues sought to be tried separately are significantly different from one another;
- (2) whether the severable issues require the testimony of different witnesses and different documentary proof;
- (3) whether the party opposing the severance will be prejudiced if it is granted; and
- (4) whether the party requesting the severance will be prejudiced if it is not granted.

*Moore v. Navillus Tile, Inc.*, 2017 U.S. Dist. LEXIS 14850, at \*35 (S.D.N.Y. Jan. 3, 2017) (McMahon, J.) (quoting *Hecht v. New York*, 217 F.R.D. 148, 149 (S.D.N.Y. 2003)).

Prejudice is not easily shown. Even in the far more defendant-protective context of a criminal trial, “[a] defendant raising a claim of prejudicial spillover bears an extremely heavy burden.” *United States v. Friedman*, 854 F.2d 535, 563 (2d Cir. 1988). The defendant must show that he may suffer prejudice so substantial that a “miscarriage of justice” will occur. *Id.* Even where a risk of prejudice can be shown, the presumption in favor of joinder as a means of achieving judicial efficiency leads most courts to employ limiting instructions to cure prejudicial spillover. *See Zafiro v. United States*, 506 U.S. 534, 539 (1993) (“less drastic measures, such as limiting instructions, often will suffice to cure any risk of prejudice”).

#### **B. None of the Relevant Factors Supports Bifurcation**

##### **(1) The reverse payment and hard switch share issues, evidence and witnesses**

The first two factors militate heavily against bifurcation because the reverse payment and hard switch were part of a single strategy – namely, delaying generic Namenda IR to shift the

market to Namenda XR, culminating in the hard switch – that involve overlapping witnesses and evidence. *See* Part II, *supra*. Bifurcation is inappropriate where issues, evidence and witnesses are “intertwined” or “overlap.” *See, e.g., Moore*, 2017 U.S. Dist. LEXIS 14850, at \*37 (denying bifurcation motion where issues were “sufficiently intertwined”); *Blech*, 2003 U.S. Dist. LEXIS 4650, at \*34 (“Separate trials are not appropriate when issues, witnesses and documentary evidence overlap.”) (internal quotation marks omitted); *Monaghan*, 827 F. Supp. at 245 (same).

Forest cites inapt cases in which the court determined that there was no genuine overlap of issues, such as *Katsaros v. Cody*, 744 F.2d 270, 278 (2d Cir. 1984) (Mot. at 5), where the Second Circuit found no abuse of discretion in the decision to bifurcate where the issues involved “different types of evidence,” as well as a separate set of claims still stuck in discovery. In *Rezende v. Citigroup Global Mkts., Inc.*, 2011 U.S. Dist. LEXIS 45475, at \*23 (S.D.N.Y. Apr. 27, 2011), the issue of the identity of ownership of a corporation did not overlap with whether a cross-claimant committed assault and battery. And in *Amato v. Saratoga Springs*, 170 F.3d 311, 316 (2d Cir. 1999) (Mot. at 9), the evidence against one co-defendant was inadmissible against the other, a circumstance absent here.

**(2) Denial of bifurcation would not prejudice Forest**

*a) Limiting instructions suffice to alleviate possible prejudice*

Forest speculatively claims that the jury “may not be able to separately analyze the evidence with respect to the reverse-payment claim by putting the separate hard-switch claim out of their minds.” Mot. at 9. This concern is unfounded and can readily be cured with limiting instructions as the Court already explained in previously rejecting Forest’s argument. Tr. of March 15, 2019 at 5:17-6:14 (ECF No. 689). *See also Blech*, 2003 U.S. Dist. LEXIS 4650 at \*40 (limiting instructions prevent potential spillover prejudice). Limiting instructions are an accepted cure to any purported prejudice from failing to bifurcate. *See Manganiello v. Agostini*,

2008 U.S. Dist. LEXIS 99181, at \*29-30 (S.D.N.Y. Dec. 9, 2008) (explaining the “fundamental proposition that a jury is presumed to follow the instructions of the trial judge”); *Zafiro*, 506 U.S. at 540 (limiting instructions suffice because “juries are presumed to follow their instructions”).

*b) Presentation of multiple issues does not constitute undue prejudice, nor will it confuse the jury*

Speculative concern that the jury may become confused or biased from hearing evidence on multiple issues does not constitute the kind of prejudice that warrants bifurcation.

“[B]ifurcation . . . is reserved for truly extraordinary situations of *undue* prejudice.” *Moore*, 2017 U.S. Dist. LEXIS 14850, at \*41-42 (quotation omitted) (emphasis in original). Thus, in *In re Veeco Instruments, Inc. Sec. Litig.*, this Court explained that “assertions about . . . the potential for confusion given the complexity of issues involved . . . and the amorphous possibility of prejudice to defendants if jurors are moved by sympathy” do not “present[] the sort of exceptional circumstances that would overcome the presumption in favor of a single trial.” 2007 U.S. Dist. LEXIS 102363, at \*3-5 (S.D.N.Y. June 28, 2007) (McMahon, J.). Otherwise, courts would “require bifurcation in every securities class action. That is surely not the practice of the courts.” *Id.* See also *Monaghan*, 827 F. Supp. at 246 (possible jury sympathy is a normal concern but not cognizable prejudice warranting bifurcation).

An example from another suppressed generic competition case illustrates the point. In *King Drug*, the direct purchaser class alleged *Walker Process* patent fraud against the brand drug manufacturer only, and also brought reverse payment claims against the brand and several generic manufacturers. Citing the potential for prejudicial spillover, one of the generic manufacturer defendants, Ranbaxy, argued that the *Walker Process* fraud claim should be severed and tried separately against the brand manufacturer defendant alone. Ex. 12, Ranbaxy Mem. at 2. Judge Goldberg denied the motion, because “significant overlapping factual issues,

judicial economy of interests and fairness weigh in favor of a single liability trial and the potential for prejudice can be adequately addressed through jury instructions.” Ex. 13, Order, *King Drug Company of Florence, Inc. v. Cephalon, Inc.*, 2:06-cv-01797-MSG (E.D. Pa. Jan. 15, 2016), ECF No. 998 at n.1.

In both of the cases Forest cites (*Solodyn* and *Nexium*, Mot. at 6), separate *damage* trials were planned for direct and indirect purchasers because the Supreme Court’s decisions in *Illinois Brick* and *Hanover Shoe* prohibit evidence of “pass on” injury to indirect purchasers from being offered in a case brought by direct purchasers. An “antitrust defendant is not permitted to introduce evidence that indirect purchasers were in fact injured by the illegal overcharge.” *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 724-25 (1977); *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 494 (1968) (antitrust defendants cannot argue that direct purchasers passed-on all or some overcharges to their customers). Here, *only* direct purchasers are going to trial. Hence the bifurcation in *Solodyn* and *Nexium* is inapplicable, and completely off point. See Ex. 14, *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-MD-2409-WGY (D. Mass.), Dec. 11, 2013 Tr. at 11:2-5 (Judge Young stating “I agree that we’re not going to be able to try damages, if damages there are, if any, for the end payors and the direct purchasers in the same proceeding. I can’t see how that would be fair.”); Ex. 15, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, MDL No. 2503 (D. Mass.), Plaintiffs’ Submission Regarding Proposed Jury Verdict Forms at 2, ECF No. 977 (proposing bifurcation to avoid “conflicting economic evidence concerning the damage theories of the direct purchasers and end payors”).

*c) Forest’s Fed. R. Evid. 404(b) analogy is inapt*

Forest asserts that “[p]ermitting the jury to hear evidence of Forest’s hard switch before adjudicating the reverse-payment claim is tantamount to permitting evidence of prior wrongful conduct at trial, which is generally inadmissible under Rule 404(b) of the Federal Rules of

Evidence.” Mot. at 9-10. The analogy is inapt, which is why Forest can find no on-point case law to support it. First, evidence concerning the hard switch is not “similar acts” evidence, nor is it offered to prove “character in conformity therewith,” so Rule 404 is not implicated in the first place. Even if it were, Rule 404(b) allows evidence of “motive, opportunity, intent, preparation, plan, [and] knowledge,” and it is clear that the reverse payment presents all of those things for the market conversion culminating in the hard switch. This Court rejected a similar argument in *Veeco* for a similar reason. *Veeco*, 2007 U.S. Dist. LEXIS 102363, at \*14 (Rule 404(b) evidence “may properly be introduced to help establish a defendant’s state of mind”).

Second, any purported prejudice can again be cured with a limiting instruction. *See Ambrose v. City of New York*, 623 F. Supp. 2d 454, 480 (S.D.N.Y. 2009) (“Any spillover prejudice to the individual officers that may be caused by the admission of Rule 404(b) evidence at trial to establish the *Monell* claim pertaining to the Individual Defendants could be cured by limiting instructions. Moreover, separate trials would not be efficient and would inconvenience the court, the jury, and the plaintiff. Accordingly, Defendants’ request to bifurcate is denied.”) (citations and quotations omitted); *United States v. Gardell*, 2001 U.S. Dist. LEXIS 16118, at \*36 (S.D.N.Y. Sep. 25, 2001) (two defendants each claimed that use of 404(b) evidence against the other would taint the jury, but severance motion denied, because “any potential prejudice can be cured by a strong limiting instruction”).

### **(3) Bifurcation Would Prejudice Plaintiffs**

Plaintiffs would be prejudiced if severance and bifurcation were granted. First, Plaintiffs would be deprived of the ability to explain to the jury the interrelatedness of the reverse payment and the hard switch. Second, Plaintiffs would be forced to try two cases *seriatim* instead of just one, which involves duplication of effort, more work, and greater expense (particularly expert witness expense, as Forest concedes, Mot. at 8) than trying this case just once.

### **C. Bifurcation Will Not Enhance Efficiency**

Forest identifies no time savings in the event of a jury finding in its favor after a separate initial trial on the reverse payment. By contrast, the obvious need for two openings, two closings, two jury charges, two rounds of directed verdict motions, and recalled witnesses makes bifurcation far less efficient. *See Blech*, 2003 U.S. Dist. LEXIS 4650, at \*42 (denying bifurcation where “Plaintiffs w[ould] be compelled to recall both of its expert witnesses, as well as reintroduce the documentary evidence upon which their opinions are based”).

Forest seeks to reassure the Court that only a single jury would be used. Plaintiffs have assumed this throughout this opposition; it is still cold comfort. In *Veeco*, this Court acknowledged that “[e]ven if the two phases could be tried to the same jury *seriatim*,” there would still be an associated “delay and administrative inconvenience.” 2007 U.S. Dist. LEXIS 102363, at \*5-6.

### **D. The Bifurcation Motion Should Be Summarily Denied Because It Is Nothing More Than an Untimely Motion for Reconsideration**

Forest acknowledges that the Court already ruled against it when it previously sought bifurcation. Mot. at 2. Forest expressly assented to the Court’s prior ruling. Tr. of Mar. 15, 2019 at 5:23 (“Understood”); *id.* at 6:7 (“OK”) (ECF No. 689). Without good cause, and without first seeking leave to do so, Forest has filed a motion for reconsideration beyond the fourteen-day limit mandated by Local Rule 6.3. “Rule 6.3 is to be narrowly construed and strictly applied so as to avoid repetitive arguments on issues that have been fully considered by the court.” *Gloria D. Dickerson v. USAir, Inc.*, 2001 U.S. Dist. LEXIS 27, at \*9 (S.D.N.Y. Jan. 4, 2001); *Moton v. Maplebear Inc.*, 2017 U.S. Dist. LEXIS 49521, at \*4-5 (S.D.N.Y. Mar. 20, 2017) (denying as untimely a motion for reconsideration); *Rullan v. N.Y.C. Dep’t of Sanitation*, 2012 U.S. Dist. LEXIS 2896, at \*5 (S.D.N.Y. Jan. 10, 2012) (same); *Grand River Enters. Six Nations, Ltd. v.*



*King*, 2009 U.S. Dist. LEXIS 52600, at \*53 (S.D.N.Y. June 16, 2009) (same). This is an adequate and independent basis to reject Forest's motion.

#### IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Forest's Motion to Bifurcate.

Dated: May 3, 2019

Respectfully Submitted:

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 3, 2019, I electronically filed the forgoing via the Court's CM/ECF system.

Respectfully submitted,

/s/ Dan Litvin  
Dan Litvin